Section 2 - Summary of Safety and Effectiveness

This submission is prepared to show equivalence between the Cordis Webster Orthogonal (predicate) and the Cardima Pathfinder (new) electrode recording devices, according to the Safe Medical Device Act of 1990.

The criteria for equivalence included comparing labeling, physical characteristics and clinical performances of the new and predicate devices as well as physical and animal testing of the new device with biocompatibility and sterilization information.

Both devices are made to aid physicians specializing in cardiac electrophysiology, cardiac surgery and interventional cardiology in the management of abnormal rhythms of the heart.

The main function of both devices is diagnostic sensing of electrical impulses in the heart muscles to provide precise, localized data. While the predicate device is also indicated for pacing, the new device is not intended for pacing and it is labeled so.

Longitudinal characteristics of both catheters are the same, both were designed to access the heart through the peripheral vasculature using the standard Seldinger technique.

Both devices are capable to change direction during advancement using proximal torque control. Leading the change in direction of the relatively stiff predicate device is a deflectable tip, while the new device is designed with a soft, shapeable tip, much like coronary guidewires.

While the 7 Fr. predicate device exposes larger electrodes to the heart, the signal from the 2.5 Fr. smaller diameter new device yields the same quality diagnostic information to the physician. Included with this submission is the clinical data and a conclusive statement from the independent reviewers supporting the equivalence claim.

Device Description

The 2.5 Fr. Pathfinder Electrode Recording Catheter is a diagnostic medical device designed to sense electrical signals by use of multiple electrodes placed on the distal end of the catheter, each of which is connected to a connector at the proximal end of the catheter by means of a conductor wire. The connector is matched with a connector cable which functions to link the catheter to a standard ECG recording/monitoring system. The device is a composite construction of biocompatible materials commonly used in other (FDA) approved catheters.

The catheter is available in 4, 8 and 16 electrode configurations and provides for a distal electrode recording length of up to 7 cm. The working outer diameter of the catheter is 2.3F or 2.5F depending upon the number of electrodes. The useable lengths are 100, 135, 150 and 200cm.

Nonclinical Tests

Bench Studies: A series of tests were performed using the FDA "Electrode Recording Catheter Preliminary Guidance, June 1994" as a guide. The tests were used to assess the mechanical and electrical properties of both the catheter and the connector cable. Mechanical testing included tensile and torsional strength, angular rotation, coil/tip stiffness and flexural fatigue. Electrical testing included electrical phase shift and dielectric voltage breakdown. All test samples met the defined acceptance criteria for each performance test. In addition to mechanical and electrical testing, a full series of biocompatibility testing was performed on final, sterilized product. Testing included cytotoxicity, hemolysis, mutagenicity, systemic/ intracutaneous/intravenous toxicity, muscle implantation, and delayed contact sensitization.

Animal Studies: A pre-clinical GLP animal study was conducted to evaluate the performance of the Pathfinder device in recording cardiac signal recording from the coronary sinus when compared to the Orthogonal device. The study demonstrated that the Pathfinder could be successfully placed in the coronary sinus, could record cardiac signals of adequate quality from the coronary sinus, and did not present any increase in device associated complications as compared to the Orthogonal catheter.

Clinical Tests

A controlled clinical investigation was conducted at two clinical sites consisting of a total of 20 patients undergoing an electrophysiology study for arrhythmia. The purpose of the investigation was to demonstrate equivalent safety and effectiveness of the Pathfinder device when compared to the Orthogonal device. The study design was to use patients as their own control, in which, in the same patient, signal recordings were obtained with the Pathfinder device immediately followed by signal recordings obtained with the Orthogonal device in the coronary sinus. To demonstrate safety and effectiveness, signal recordings, device maneuverability/placement, and complications were compared. The results indicated that the Pathfinder device is substantially equivalent to the Orthogonal device with respect to safety and effectiveness.

Conclusions Drawn from Nonclinical and Clinical Tests

The results of the nonclinical and clinical tests summarized in sections (b)(1) and (b)(2) above, indicate that the Cardima Pathfinder Electrode Recording Catheter exhibits substantially equivalent safety and effectiveness when compared to the Cordis Webster Orthogonal Electrode Recording Catheter.